

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC., A
DELAWARE CORPORATION;
Plaintiff

-VS-

BRAIN FREQUENCY LLC, A TEXAS
LIMITED LIABILITY COMPANY
Defendant

SA-23-CV-00626-XR

ORDER

On this date, the Court considered Defendant Brain Frequency LLC’s (“Brain”) motion for partial summary judgment (ECF No. 30), Plaintiff Wave Neuroscience, Inc’s (“Wave”) response (ECF No. 33), and Brain’s reply (ECF No. 36). After careful consideration, the Court **DENIES** the motion.

BACKGROUND

This infringement suit involves patents for methods to provide Transcranial Magnetic Stimulation (“TMS”) to improve a variety of brain disorders and cognitive functioning by targeting certain metrics obtained by an electroencephalogram (“EEG”). According to Wave, Brain infringed three patents: (i) U.S. Patent No. 8,926,490 (the “’490 Patent”), (ii) U.S. Patent No. 9,015,057 (“’057 Patent”), and (iii) U.S. Patent No. 11,311,741 (“’741 Patent”).¹ While Wave asserts apparatus and method claims, only the method claims in the ’408 and ’737 Patents are at issue here.² ECF No. 30 at 4.

¹ Wave also claimed infringement of U.S. Patent No. 10,029,111 (“111 Patent”), but the parties represented at the *Markman* hearing that they would be stipulating to the dismissal of these claims. No written stipulation has been filed with the Court to date.

² Wave also asserted method claims for the '111 Patent, but those are not at issue anymore. *See infra* note 1.

Brain seeks summary judgment on Wave’s method claims under 35 U.S.C. § 287(c) (“Physicians’ Immunity Statute”), which immunizes a medical practitioner or related health care entity from liability in a patent infringement suit for performance of a medical activity.³ For the purposes of this motion, the Court assumes the patents-in-suit are valid and that Brain infringed them. Accordingly, it considers the scope of § 287(c) and whether Brain is a “related health care entity” as defined in the statute. Under Brain’s interpretation, a private company is immune from infringement liability for medical method patents if it licenses the infringing product to—has a contractual relationship with—a medical practitioner who performs the treatment.

The Physicians’ Immunity Statute is broad, but it is not limitless. Because Brain is a software company that only licenses its product to medical providers and disclaims any relation to the providers or their treatment, it falls outside this realm and cannot avail itself of Section 237(c)’s immunity.

LEGAL STANDARD AND RELEVANT FACTS

The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56. The relevant facts are undisputed.⁴

³ See *Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811, 818 (S.D. Tex. 2008) (noting that “Section 287(c) is properly understood as an immunity provision,” which “avoids liability” but does not “deny the injury”) (citing Charles Alan Wright & Charles H. Koch, Jr., 33 FEDERAL PRACTICE AND PROCEDURE § 8320 (3d ed. 2006)).

⁴ The parties contest whether Brain, along with licensing its software, also distributes TMS machines. Compare ECF No. 30-1 ¶ 52 (“Brain . . . does not provide or sell machines, or parts of machines, such as TMS and EEG devices”) with ECF No. 33 at 16 (“Brain Frequency itself offers to lease the required [TMS] device to its licensees”). Brain admits that “there is language in the license agreement about leasing products” but maintains that it “was left in extraneously.” ECF No. 36 at 6. These machines are regulated by the Federal Food, Drug, and Cosmetic Act. See ECF No. 33 at 16–17 (“Brain Frequency’s own contract demonstrates that it ‘sell[s], offer[s] to sell, or market[s]’ the MagVenture TMS device,” which is “regulated under the Federal Food, Drug, and Cosmetic Act.”). While this is related to Wave’s argument that Brain is exempted under § 287(c)(3), the Court need not address this issue because it resolves the motion on other grounds.

Brain’s founder, Shannon Malish, developed the Brain Frequency Software which analyzes a patient’s EEG measurements to more accurately indicate areas of the brain that are negatively impacted. ECF No. 30-1 ¶¶ 49–50. This software then provides “unique analytics of the patient’s data in order to more effectively diagnose and target how TMS should be used for much more effective results.” *Id.* ¶ 51.

Brain, however, does not itself provide medical advice, diagnoses, or medical treatment. It does not use its software to analyze a patient’s EEG measurements. Nor does it use its software to target a subject’s TMS treatment. Instead, Brain is only a software company. ECF No. 30-1 ¶ 52 (Brain “*only* provides software[.]”). It profits off the commercialization of its software by licensing it to individual medical practitioners or medical organizations that exclusively treat patients with mental disorders. *Id.* ¶ 53. It is true that each of its licensees are medical practitioners or those acting under the direction and supervision of medical practitioners who are licensed by the State of Texas or other states. *Id.* ¶ 55. And each licensee provides treatment or diagnosis using Brain’s software pursuant to a contractual relationship between Brain and the practitioners themselves. *Id.* ¶ 57. But none of these medical practitioners are employees of Brain, nor do they perform the treatment in connection with Brain. They do not interface with Brain when using the software. Brain is not involved in the treatment of patients in any way outside of licensing its software to these practitioners. Indeed, Brain’s customer contract expressly states that

NEITHER BRAIN FREQUENCY NOR THE BRAIN FREQUENCY SYSTEM PROVIDES MEDICAL ADVICE, INSTRUCTION OR DIAGNOSIS OF A MEDICAL CONDITION, OR INSTRUCTION FOR TREATMENT OF A MEDICAL CONDITION.

ECF No. 30-8 at 1, 10.

ANALYSIS

I. Physicians’ Immunity Statute

Section 281 of the Patent Act provides that “[a] patentee shall have remedy by civil action for infringement of his patent.” 35 U.S.C. § 281. Sections 283, 284, and 285 provide for injunctive relief, damages, and attorney’s fees as a remedy for infringement. 35 U.S.C. §§ 283–285. Under the Patent Act, a medical method is generally patentable, so long as it is not patent-ineligible subject matter.

The Physicians’ Immunity Statute provides immunity to liability for certain actors for medical method patent infringement. 35 U.S.C. § 287(c). The text of Section 287(c) states that

[w]ith respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against the medical practitioner or against a related health care entity with respect to such medical activity.

There are essentially two substantive elements of the statute: (1) that the defendant be a “medical practitioner” or a “related health care entity” as defined in the statute; and (2) that the defendant is accused of infringing based on the performance of a “medical activity,” as defined in the statute. *Id.* § 287(c)(1).

The parties do not dispute that the use of Brain Frequency Software for TMS treatment is a “medical activity.” *See id.* § 287(c)(2)(A) (defining “medical activity” as “the performance of a medical or surgical procedure on a body,” with three exceptions inapplicable here). It is also uncontested that Brain is not a “medical practitioner,” as Brain is not licensed nor acting under the direction of any licensed person to perform medical activity. *See id.* § 287(c)(2)(B). The issue turns solely on whether Brain is a “related health care entity.”⁵

⁵ Because the Court finds that Brain is not a “related health care entity,” the Court need not reach Wave’s second argument: that Brain cannot avail itself of immunity under § 287(c)(3) because it is engaged in the “commercial sale

II. Brain is Not a “Related Health Care Entity”

Two defined terms are relevant here: a “related health care entity” and a “professional affiliation.” A “related health care entity” is “an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.” 35 U.S.C. § 287(c)(2)(C). A “professional affiliation” refers to “staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.” 35 U.S.C. § 287(c)(2)(D).

Brain asserts it is a “related health care entity” because it maintains “contractual relationships and associations under which the practitioners provide medical diagnosis and treatment of patients.” ECF No. 30 at 8–9. Brain insists that, by licensing its software, it qualifies as “an entity” with which “medical practitioners” have a “professional affiliation.” In support, Brain relies on *Emtel Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811 (S.D. Tex. 2008) and the plain text of the statute. Wave rejects Brain’s reading of *Emtel*. It claims that the Physicians’ Immunity Statute is not so broad and instead distinguishes between types of contractual relationships, only some of which create a “professional affiliation.” ECF No. 33 at 11–13. The Court agrees.

A. *Emtel* Does Not Support Brain

In *Emtel Inc. v. Lipidlabs, Inc.*, the court held that telemedicine support service companies were “related health care entities” under Section 287(c). 583 F. Supp. 2d 811 at 825. There, the telemedicine companies entered into two sets of agreements: (i) affiliation agreements with

... or distribution of a machine” that is “regulated under the Federal Food, Drug, and Cosmetic Act.” ECF No. 33 at 18; *see supra* note 4.

physicians or physician groups and (ii) separate agreements with remote medical care facilities. *Id.* at 824. In the agreements with the medical care facilities, the telemedicine companies agreed to provide outsourced medical diagnosis or treatment from the affiliated physicians. *Id.* at 824. And the agreements with these physicians or physician groups (who were independent contractors) required the doctors to provide such services. *Id.* at 817, 824. Under this two-way contractual relationship, the court held the telemedicine companies were “related health care entities” because the contracts called for the companies to “match a request for medical assistance from a remote medical facility with an affiliated physician who has a particular responsive specialty,” where these physicians “use[d] videoconferencing to view a patient.” *Id.* at 825. The court contrasted this relationship with one where medical providers “merely agree to use [an entity’s] services or property.” *Id.* at 824. In other words, the physicians provided their services in connection with the telemedicine companies which acted as remote clinics, and thus did more than merely use the technology services to reach the patients.

Unlike *Emtel*, Brain plays no role in the provision of medical services to the patients. The medical providers do not interface with Brain when providing the treatment. And Brain’s licensing contract explicitly disclaims any role in the treatment or diagnosis with the medical providers. Here, the medical providers that contract with Brain “merely agree to use [Brain’s] services or property in medical practice,” a scenario that *Emtel* confirmed falls outside of the scope of Section 287(c). *Id.* at 824–25. Brain’s reading of *Emtel*, then, is unavailing. The Court now turns to the statute’s text, which Brain asserts compels immunity nonetheless.

B. The Text and Purpose of Section 287(c) Support Wave

Brain’s argument is quite simple: its contractual relationships with medical providers establish professional affiliations with such providers that render Brain a “related healthcare

entity” entitled to immunity under Section 287. But Brain’s reading is inconsistent with the statute’s text and would extend Section 287’s immunity beyond its intended reach. Both defined terms—“related healthcare entity” and “professional affiliation”—limit what type of “contractual relationship” suffices under the statute.

1. Section 287(c)’s Text

Statutory interpretation necessarily begins with the statute’s text. *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999). “[W]hen ‘the statute’s language is plain, the sole function of the courts . . . is to enforce it according to its terms.’” *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989)). “In construing a statute, a court should give effect, if possible, to every word and every provision Congress used.” *Asadi v. G.E. Energy (USA)*, 760 F.3d 620 (5th Cir. 2013). The ordinary meaning of statutes is not determined by interpreting the relevant words “in a vacuum” but with reference to the statutory context and the statute’s “structure, history, and purpose,” all read through the lens of basic common sense. *Abramski v. United States*, 573 U.S. 169, 179 (2014).

Brain argues that its contractual relationship with medical practitioners creates a “professional affiliation” because the treatment is “facilitated, in part” by Brain. ECF No. 36 at 3. To start, the word “facilitate” does not appear in the text of Section 287(c). “When Congress takes the trouble to define the terms it uses, a court must respect its definitions as ‘virtually conclusive.’” *Dep’t of Agric. Rural Dev. Rural Hous. Serv. v. Kirtz*, 601 U.S. 42, 59 (2024) (quoting *Sturgeon v. Frost*, 587 U.S. 28, 56 (2019)). While Congress explicitly defined “professional affiliation” to include a “contractual relationship,” 35 U.S.C. § 287(c)(2)(D), it did not define use “contractual

relationship” in a silo. It is used it in a series of like terms, each of which has a modifier that defines and limits their scope. Multiple canons of statutory construction guide this conclusion.

First, “contractual relationship” is used in the same phrase as “employment,” such that a “professional affiliation” is defined, in part, as “employment or contractual relationship.” *Id.* The use of “or” indicates that “contractual relationship” is distinct from and not confined to employment. *See United States v. Nazerzadeh*, 73 F.4th 341, 344 (5th Cir. 2023) (“The word [or] ‘indicates alternatives and requires that those alternatives be treated separately.’”) (citing *Dacostagomez-Aguilar v. U.S. Atty. Gen.*, 40 F.4th 1312, 1316 (11th Cir. 2022)). But “the canon of *noscitur a sociis* teaches that a word is ‘given more precise content by the neighboring words with which it is associated.’” *Fisher v. United States*, 603 U.S. 480, 487 (2024) (quoting *United States v. Williams*, 553 U.S. 286, 294 (2008)). In this context, “contractual relationship” is given this “more precise content,” *id.*, by its neighboring “employment,” and so is sensibly read to mean a relationship that is similar in kind to an employee-employer relationship.

In some circumstances, two distinct words connected by a disjunctive may be less suited for the application of *noscitur a sociis*. *See Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 288 (2010) (finding use of *noscitur a sociis* “unpersuasive” because “[a] list of three items, each quite distinct from the other no matter how construed, is too short to be particularly illuminating.”); *but see MBIA Ins. Corp. v. FDIC*, 708 F.3d 234, 241–42, 245 (D.C. Cir. 2013) (declining to accept a party’s argument that “a list of two words is an inappropriate occasion for application of *noscitur a sociis*”).

Even if “employment” and “contractual relationship” were “quite distinct,” however, Section 287(c)(2)(D) situates “contractual relationship” in the context of other terms, including “staff privileges, medical staff membership . . . partnership or ownership interest, [and] academic

appointment.” 35 U.S.C. § 287(c)(2)(D). Thus, “contractual relationship” is at a minimum similar in kind to these other relationships. And these terms all have in common that the “medical practitioner provides the medical activity *on behalf of, or in association with*, the health care entity.” *Id.* (emphasis added).” Applying the series-qualifier canon supports the conclusion that this modifier applies to each term in the series.⁶

This context adds additional meaning to “contractual relationship.” The term “association” is defined as “[t]he action of combining together for a common purpose.” THE OXFORD ENGLISH DICTIONARY (2d ed. 1989). To “associate” is defined as “to join . . . in common purpose, action or condition.” *Id.* And “behalf” is defined as “on the side of” or “[o]n the part of (another).” *Id.* As used as idioms, the terms refer to “in connection with or together with” and “in the interest of” or “as a representative of,” respectively. See *In Association With*, <https://www.merriam-webster.com/dictionary/in%20association%20with>; *On Behalf Of*, <https://www.merriam-webster.com/dictionary/on%20behalf%20of>. Construing “contractual relationship” to refer to *any* contractual relationship would give “unintended breadth to the Act[] of Congress.” *Jarecki v. G.D. Serle & Co.*, U.S. 303, 307 (1961). Further, the definition of “contractual relationship” were as broad as Brain believes, much of § 287(c)(2)(D) would be rendered surplusage: “staff privileges, medical staff membership . . . partnership or ownership interest, [and] academic appointment,” are

⁶ That canon provides that “[w]hen there is a straightforward, parallel construction that involves all nouns or verbs in a series,’ a modifier at the end of the list ‘normally applies to the entire series,’” *Facebook, Inc. v. Duguid*, 592 U.S. 395, 402 (2021) (quoting A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 147 (2012)). So long as the modifying clause “is applicable as much to the first and other words as to the last,” “the natural construction of the language demands that the clause be read as applicable to all.” *Paroline v. United States*, 572 U.S. 434, 447 (2014) (quoting *Porto Rico Railway, Light & Power Co. v. Mor*, 253 U.S. 345, 348 (1920)). Every specified “professional affiliation” in § 287(c)(2)(C) is one in which the medical practitioner provides the medical activity “on behalf of, or in association with” the health care entity. For example, a medical provider who has staff privileges or membership at a hospital, or is a partner in a medical practice, or has an academic appointment to either, all perform the medical activity in the interest of, as a representative of, or in connection with or together with that entity. As the examples of “professional affiliation” are an “integrated list,” *Facebook*, 592 U.S. at 404, the modifier applies to each.

all contractual relationships between the medical provider and the health care entity. Congress would not need to add all these other terms if it interpreted “contractual relationship” so broadly.

Thus, the Court does not read Section 287(c)(2)(D)’s “professional affiliation” to encompass any contractual relationship whatsoever. Under Section 287(c)(2)(D), Brain’s “contractual relationship” must be one that is similar in kind to an employment relationship, or, at a minimum, one in which the medical providers perform the treatment “on behalf of, or in association with” Brain. This is not the case. A licensor is different in kind from an employee-employer relationship. And the medical providers who license Brain’s software do not provide the TMS treatment “on behalf of, or in association with” Brain. They do not join with or perform the treatment for Brain, and Brain’s contract explicitly disclaims any involvement with the medical practitioners or the treatment itself. Brain lacks a “professional relationship” with the medical providers as contemplated by Section 287(c).

Section 287(c)(2)(C) offers further support for the Court’s understanding of the kind of contractual relationship that creates a “professional affiliation” by providing specific examples of “related health care entities” that are covered under the statute: “a nursing home, hospital, university, medical school, health maintenance organization, group, medical practice, or a medicine clinic.” 35 U.S.C. § 287(c)(2)(C). While not exhaustive because the “structure suggests that the examples provided are only a subset of [entities] encompassed by the [statute],” *RSBCO v. United States*, 104 F.4th 551, 558 (5th Cir. 2024), these are all places or entities that the medical provider is themselves a part of—they provide the medical activity “on behalf of, or in association with” these entities.

Unlike the examples in § 287(c)(2)(C) in which the medical practitioner is involved in some way with the “health care entity,” such that it works at or with the entities, Brain merely has a business relationship with the medical providers.

2. The Legislative History of Section 287(c)

The legislative history of Section 287(c) confirms that it “was intended to protect physicians from infringement suits for the procedures they use to treat patients[.]” *Emtel, Inc.*, 583 F. Supp. 2d at 822 (citing 142 Cong. Rec. S12023–01, *S12023, 1996 WL 553950 (daily ed. Sept. 30, 1996) (statement of Sen. Frist)). Signed in 1996, Section 287(c) responded to the controversial case of *Pallin v. Singer*, the first infringement case involving a medical method patent. No. 5:93-202, 1995 WL 608365 (D. Vt. 1995). In *Pallin*, Dr. Samuel Pallin sued a fellow physician, Dr. Jack Singer, and the clinic he was affiliated with, for performing Dr. Pallin’s patented cataract surgery incision. *Id.* at *1–2. Even though *Pallin* was ultimately dismissed by a consent order invalidating the claims and enjoining Dr. Pallin from enforcing his patent, *see* No. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28, 1996), it renewed discussion over whether medical methods should be patentable in the first place. On the one hand, the medical community pushed to outlaw the practice of patenting medical and surgical procedures. *See Emtel, Inc.*, 583 F. Supp. 2d at 820 & n.4 (citing H.R. 1127, 104th Cong. (1st Sess. 1995)). But the patent bar and biotechnology groups pushed back, worried that such an amendment would erode their patent rights. *See id.*

After multiple bills were introduced in both the House and Senate without passage, Section 287(c) represented a compromise that left in place the definitions of patentable subject matter (§ 101) and infringement (§ 271) but provided immunity for infringing activity by select actors. According to Senator Bill Frist—the legislation’s chief sponsor in the Senate—the final legislation

“simply prevent[ed] the enforcement of [pure procedure medical patents] against health professional [s] or their affiliated facilities.” 142 Cong. Rec. S12023–01, *S12023, 1996 WL 553950 (daily ed. Sept. 30, 1996)). It is true that “[f]or practical purposes . . . [the Physicians’ Immunity Statute] [has] operate[d] as an exclusion from patentable subject matter,” because “the grant of patent rights in such inventions does not include the right to maintain suit against a significant — perhaps the only significant — class of persons who will be likely to infringe.” 1 Moy’s Walker on Patents § 5:42 (4th ed.). But protecting this class—the practitioners who use medical method patents and the facilities through which they work—does not imply that the statute extends to *any* company in the health care industry involved with such patents. A company that only sells or licenses infringing products to medical providers, without more, falls outside this class. There is no evidence that Congress understood Section 287(c) to immunize such actors.

Under Brain’s theory, a company that sells or licenses products to practitioners that consist of medical methods would be a “related health care entity,” regardless of the nature of its relationship with the medical practitioner or role in treatment. Brain’s reading would turn § 287(c) from a statute that “immunize[s] the practitioner and the institutions they work for from all liability for infringement in connection with a medical treatment,” *Lamson v. United States*, 117 Fed. Cl. 755, 762 (2014), to one that offers blanket immunity to all companies that infringe medical method patents writ large. Whether that is a good policy or not is not for the Court to decide. The Court does not believe § 287(c), as enacted, extends so far.

CONCLUSION

For the foregoing reasons, Brain’s motion for partial summary judgment (ECF No. 30) is **DENIED**.

IT IS SO ORDERED.

SIGNED this 21st day of November, 2024.

A handwritten signature in blue ink, consisting of a large, stylized loop followed by a horizontal stroke and a small flourish.

XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE